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Guidelines for the safe prescribing of treatments used in gender dysphoria for Trans Women

The guidelines below constitute a collaborative care protocol for patients undergoing gender transition. These guidelines have been developed following release of a National (UK) Standards of Care document by an interdisciplinary committee (RCPsych CR181 www.rcpsych.ac.uk/files/pdfversion/CR181.pdf). These guidelines ensure good care between the tertiary care service for gender dysphoria and patients in primary care.

Service users should be encouraged to stop smoking, take regular exercise, have a sensible diet, and consume no more than 14 units of alcohol per week.

Medication

The gender clinician will obtain informed consent. The specialist clinician will provide the initial prescription or this can be from the GP if they are in agreement with collaborative care prescribing. The prescriber is responsible for ensuring regular blood tests are taken in accordance with the protocol. If this is undertaken by the GP, advice can be obtained from the gender clinic on any results outside of the expected levels (as indicated in the protocol) or action taken *as per contemporary UK medical practice.*

Typical treatments that are licensed but are very often being used in an off license manner would be for:

1. ***Oestrogen*** - Dosage of oestrogen depends on results of circulating oestradiol levels – see below.

Oral Estradiol (1– 6mg oral daily). *Note increase of clotting factors; antiepileptic and antifungal medication decrease E2 levels;*

Or, transdermal Estradiol patches (50mcg – 150mcg applied twice a week). This is particularly for patients over 40 years (lower risk of thrombosis) e.g. Estraderm 50 = 50mcg over 24 hours.

Or, transdermal Oestrogel. 2 measures rubbed onto the shoulder, outer arm or mid-inner thigh daily = 1.5mg oestradiol (use 2-4 measures daily)

2. ***GnRH analogue*** - inhibits secretion of pituitary gonadotrophin and testosterone secretion. *Note possible increase the risk of diabetes and cardiovascular disease.*

Leuprorelin 3.75mg subcutaneously (s.c.) or intramuscularly (i.m.) four weekly or 11.25mg s.c. /i.m. twelve weekly

Additional therapies, that may be helpful, include…

• **Cyproterone Acetate** - (50mg – 100mg orally daily) – *NB monitor LFT's before and throughout treatment. Also, CT head scan to check for meningioma if long term cyproterone.*

• **Spironolactone** (100mg – 200mg orally daily) may be required for additional androgen receptor blockade – *NB monitor electrolytes and K+ before and throughout treatment. Risk of possibly hepatoma risk (animal data).*

N.B. cyproterone and spironolactone are not recommended for long term therapy unless there are no good alternatives as chronic side effects may ensue.

Progesterone is not indicated as no biologically significant progesterone receptor sites exist for biological males.

• **Finasteride** (5mg orally daily) – blocks conversion of testosterone (which may derive from adrenal androgens in the absence of secreting testes) to the more active di-hydrotestosterone (DHT). This agent can discourage male pattern hair loss and testosterone dependent body hair growth. *NB reports of breast cancer & effect on cognitive & sexual function.*

Monitoring Tests

• *Baseline:* Blood pressure, full blood count, urea and electrolytes, liver function tests, fasting blood glucose, lipid profile, serum free T4, TSH, testosterone, oestradiol (should be less than 100pmol/l), prolactin (normal: 50 – 400mU/L)

• *Monitoring*:

- On a six monthly basis for three years and then yearly depending on clinical assessment and results. Provision of prescription is contingent on satisfactory tests, namely: Blood pressure, full blood count, urea and electrolytes, liver function test, fasting glucose, lipid profile, testosterone, serum estradiol *24 hours after a tablet or 48 hours after application of a patch or 4-6 hours after applying the gel* (levels should be in the region of 400-600 pmol/L), prolactin (should be less than 400mU/L).
- Longer term: Monitoring for osteoporosis (DEXA scan), breast and prostate carcinoma required *as per contemporary UK medical practice.*

Surgery

• Stop hormones 4 weeks before surgery and cover with a single dose of leuprorelin 3.75mg s.c. /i.m. Hair regrowth can occur when the effects of GnRH agonist wear off after four weeks.

• Hormones should be resumed four weeks post op if there are no complications (as above).

• Anti-androgen usually not required but androgens may still be significantly derived from adrenals – finasteride as above can be prescribed if androgen effects are still evident.

• Medication and tests needed for life as described above on 6 monthly basis for 3 years, then yearly if well (see monitoring above for further guidance).

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Further resources

Endocrinology Service, Royal Hallamshire Hospital. Contact Dr. William Bennet FRCPE 0114 271 4840

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